# Proposed Decision Memo for Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting (CAG-00085R3)

# Decision Summary

**Summary of Proposed Changes**

The Centers for Medicare and Medicaid Services (CMS) proposes the following changes to the national coverage determination (NCD) for carotid artery stenting:

- Restrict the current coverage for patients who are at high risk for carotid endarterectomy (CEA) and have symptomatic carotid artery stenosis ≥ 70% to patients who are less than 80 years of age;
- Expand coverage to patients who are at high risk for CEA and have asymptomatic carotid artery stenosis ≥80% and are less than 80 years old;
- Establish that the surgeon performing the surgical consultation that determines a patient's high risk status must be properly credentialed to perform CEA as determined by the facility.

CMS proposes the following clarifications to the current NCD:

- CAS is only covered when used with an embolic protection device and is, therefore, not covered if deployment of the distal embolic protection device is not technically possible;
- The five facility certification requirements are unchanged. We propose to modify the process for completing the certification and recertification process in the NCD Manual.

CMS proposes to maintain current coverage for CAS as follows:

- Patients at high risk for CEA who have symptomatic carotid artery stenosis between 50-70%;
- Patients who are ≥ 80 years of age with either symptomatic stenosis ≥70% or asymptomatic stenosis ≥ 80% in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201), the clinical trial policy (Medicare NCD Manual 310.1), or the National Coverage Determination on CAS post approval studies (Medicare NCD Manual 20.7B3);
- CAS for patients who are not at high risk for CEA in the opinion of a surgeon credentialed to perform carotid endarterectomy remains covered only in FDA-approved Category B IDE clinical trials under 42 CFR 405.201 or under the clinical trial policy.

This proposed decision only changes coverage criteria in section B4 of the Medicare NCD Manual for CAS (20.7). Coverage as determined in the other sections of 20.7 will continue without modification.

The proposed NCD language can be found in Section IX of this decision memorandum.

We are requesting public comments on this proposed determination pursuant to Section 731 of the Medicare Modernization Act. We are particularly interested in comments that include new evidence we have not reviewed here. After considering the public comments and any additional evidence we will make a final determination and issue a final decision memorandum.

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# Proposed Decision Memo

TO: Administrative File: CAG 00085R3
Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting

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SUBJECT: Proposed Coverage Decision Memorandum for Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting

DATE: February 1, 2007

**I. Proposed Decision**

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**II. Background**

Each year about 700,000 people in the United States experience a new or recurrent stroke. About 500,000 of these are first attacks and 200,000 are recurrent attacks (Thom, 2006). The term stroke refers to a "group of cerebrovascular disorders in which part of the brain is transiently or permanently affected by ischemia or hemorrhage, or in which one or more blood vessels of the brain are primarily affected by a pathologic process, or both" (Topol, 2002). There are three main categories of strokes: cerebral infarction (greater than 80%), intracerebral hemorrhage, and subarachnoid hemorrhage. Of the cerebral infarctions, "20% to 30% are due to atherothrombosis or thromboembolism from the extracranial or intracranial vessels" (Topol, 2002).

Treatment of carotid artery stenosis is important in preventing stroke. Currently, three mechanisms are commonly used to treat carotid stenosis; medical therapy, carotid endarterectomy (CEA), and carotid artery stenting (CAS). CEA is a surgical procedure used to prevent stroke in which the surgeon removes fatty deposits or ulcerated and stenotic plaques from the carotid arteries, the two main arteries in the neck supplying blood to the brain. Although carotid artery stenosis is an important risk factor, it was estimated that "approximately 20% and 45% of strokes in the territory of symptomatic and asymptomatic carotid arteries with 70% to 99% stenosis, respectively, are unrelated to carotid stenosis" (Barnett, 2000). In these patients, optimal medical therapy would be most important since CEA does not reduce lacunar and cardio embolic strokes.

Carotid artery stenting is performed with a catheter, usually inserted through the femoral artery, and threaded up to the carotid artery beyond the area of narrowing. A distal embolic protection device or filter is usually placed first to catch emboli or debris that may dislodge during the procedure. A self-expandable or balloon-expandable, metal mesh stent is then placed to widen the stenosis and the protection device is removed.

On August 2, 2006, CMS accepted a formal request for a national coverage analysis (NCA) for percutaneous transluminal angioplasty (PTA) of the carotid artery concurrent with stenting. In the past six years, CMS has expanded coverage of PTA and CAS through three separate NCDs.

Under the current policy, patients at high risk for CEA who have symptomatic carotid artery stenosis ≥ 70% are covered for procedures performed using FDA-approved CAS systems and embolic protection devices in facilities approved by CMS to perform CAS procedures. In addition, patients at high risk for CEA with symptomatic carotid artery stenosis between 50% and 70% and patients at high risk for CEA with asymptomatic carotid artery stenosis ≥ 80% are covered in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201), as a routine cost under the clinical trials policy (Medicare NCD Manual 310.1), or in accordance with the NCD on CAS post approval studies (Medicare NCD Manual 20.7 B3).

Under the current policy, CMS also requires that each facility certify every two years that it meets the minimum facility standards outlined in the March 17, 2005 NCD. Those standards are:

- Facilities must have necessary imaging equipment, device inventory, staffing, and infrastructure to support a dedicated carotid stent program.
- Advanced physiologic monitoring must be available in the interventional suite.
- Emergency management equipment and systems must be readily available in the interventional suite.
- Each institution should have a clearly delineated program for granting carotid stent privileges and for monitoring the quality of the individual interventionalists and the program as a whole.
- The facility or a contractor to the facility must collect and analyze data on all carotid artery stenting procedures done at that particular facility.

CMS allows initial certification that these standards are met if a letter is submitted to CMS attesting that:

1. The facility was an FDA approved site that enrolled patients in prior CAS IDE trials, such as SAPPHIRE, and ARCHER; or
2. The facility is an FDA approved site that is participating and enrolling patients in ongoing CAS IDE trials, such as CREST; or
3. The facility is an FDA approved site for one or more FDA post approval studies; or
4. The facility is a non-FDA approved facility that meets the minimum facility standards;

and, that the facility has established a mechanism for data analysis on all CAS procedures performed.

Subsequent to the NCD, CMS provided greater detail to approved facilities on the data analysis requirement and the recertification process. We will discuss this in detail in the Section XIII. Analysis.

The requestor, Guidant Endovascular Solutions, which has since become part of Abbott Neurovascular Laboratories, requested the following changes to the CAS coverage policy:

- *Provide coverage of CAS for the treatment of carotid artery disease in high surgical risk patients who are symptomatic with ≥ 50% stenosis or asymptomatic ≥ 80% stenosis and determined by the treating physician to require carotid revascularization.*
- *Remove the language in the current policy stating the patient be a poor candidate for CEA 'in the opinion of a surgeon.'*

CMS will also use this opportunity to explore the possibility of establishing a more formal facility recertification process.

**III. History of Medicare Coverage**

**History of Medicare Coverage for Percutaneous Transluminal Angioplasty**
Over the past six years, Medicare has expanded coverage for PTA and stenting of the carotid artery. Medicare first covered PTA of the carotid artery concurrent with stent placement in accordance with the FDA-approved protocols governing Category B Investigational Device Exemption (IDE) clinical trials and later in FDA required post approval studies (Medicare NCD Manual 20.7B2, B3).

**Current Medicare Coverage of Percutaneous Transluminal Angioplasty**
Effective March 17, 2005, Medicare expanded coverage of PTA of the carotid artery when performed on patients at high risk for CEA who also have symptomatic carotid artery stenosis ≥70% only when performed in a CMS approved facility for CAS with FDA-approved carotid artery stenting systems and embolic protection devices (Medicare NCD Manual 20.7B4).

Effective November 6, 2006, Medicare established coverage for PTA and stenting of intracranial vessels for the treatment of cerebral artery stenosis ≥50% in patients with intracranial atherosclerotic disease when furnished in accordance with FDA-approved protocols governing Category B IDE clinical trials. All other indications for PTA with or without stenting to treat obstructive lesions of the vertebral and cerebral arteries remain noncovered.

**Reconsideration**
Guidant Corporation/Abbott Vascular Solutions requested that CMS reconsider the current coverage policy for CAS. They specifically request broad coverage for high surgical risk patients meeting the FDA-approved indications for use as well as the removal of the language 'in the opinion of a surgeon' in the current NCD.

**Discussion of Related NCDs**
Medicare's NCD for PTA concurrent with carotid stenting can be found in NCD Manual 20.7. Medicare's NCD for PTA concurrent with carotid stenting in FDA post approval studies can also be found at NCD Manual 20.7B3.

**Benefit Category**
For an item or service to be covered by the Medicare program, it must meet one of the statutorily defined benefit categories outlined in the Social Security Act. PTA of the carotid artery concurrent with stenting, at a minimum, falls under the benefit category set forth in section §1861(b)(3) (inpatient hospital services), a part A benefit under §1812(a)(1) and §1861(s)(1) (physician services), a part B benefit. This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

**IV. Timeline of Recent Activities**

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| August 2, 2006 | CMS accepts Guidant Corporation/Abbott Vascular Solutions' formal NCD reconsideration request for expanded coverage of carotid artery stenting with distal embolic protection. The tracking sheet is posted and the initial 30-day public comment period begins. |
| September 1, 2006 | Initial 30-day public comment period closes. |
| February 1, 2007 | Proposed decision memorandum is posted and the 30-day public comment period begins. |

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**V. FDA Status**

Currently, three carotid stenting systems, comprised of the balloon angioplasty, stent, and embolic protection device, are approved for market by the FDA. These FDA-approved carotid stent systems are indicated for the improvement of lumen diameter in patients with occlusive carotid artery disease who are considered at high risk for CEA and are 1) symptomatic with ≥ 50% stenosis; or 2) asymptomatic with ≥ 80% stenosis.

**VI. General Methodological Principles**

When making national coverage decisions, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service falling within a benefit category is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. The critical appraisal of the evidence enables us to determine to what degree we are confident that: 1) the specific assessment questions can be answered conclusively; and 2) the intervention will improve health outcomes for patients. An improved health outcome is one of several considerations in determining whether an item or service is reasonable and necessary.

A detailed account of the methodological principles of study design that the agency utilizes to assess the relevant literature on a therapeutic or diagnostic item or service for specific conditions can be found in Appendices. In general, features or clinical studies that improve quality and decrease bias include the selection of a clinically relevant cohort, the consistent use of a single good reference standard, and the blinding of readers of the index test, and reference test results.

Public comments sometimes cite the published clinical evidence and give CMS useful information. Public comments that give information on unpublished evidence such as the results of individual practitioners or patients are less rigorous and therefore less useful for making a coverage determination. CMS uses the initial public comments to inform its proposed decision. CMS responds in detail to the public comments on a proposed decision when issuing the final decision memorandum.

**VII. Evidence**

## A. Introduction

In this reconsideration, we considered studies and evidence that were published after the prior decision that addressed carotid artery stenting in 2005 (NCD 20.7B4).[1] There have been several studies reported since the prior decision. The most commonly considered health outcomes have included mortality, stroke, myocardial infarction (MI) and adverse events. As noted in the prior decision, patients enrolled in the clinical studies have been generally classified by the presence or absence of symptoms from their carotid artery stenosis. This continues to be an appropriate distinction given the differing risks of stroke, indications for treatment, and benefits of intervention. Since this is a reconsideration, we have taken the opportunity to re-examine not only what was restricted but also what was covered, the requirements of coverage, and aspects of physician training and facility certification. Following the classification of the prior decision, this National Coverage Analysis (NCA) focuses on the following main questions:

- Is the evidence sufficient to conclude that PTA with carotid artery stenting improves health outcomes for patients who are at high risk for CEA surgery with symptomatic carotid artery stenosis ≥ 50%?
- Is the evidence sufficient to conclude that PTA with carotid artery stenting improves health outcomes for patients who are at high risk for CEA surgery with asymptomatic carotid artery stenosis ≥ 80%?

In addition, during the review of the evidence, a striking finding about the outcomes of CAS in patients ≥ 80 years of age became apparent and indicated the need for an additional coverage question as follows:

- Is the evidence sufficient to conclude that PTA with carotid artery stenting improves health outcomes for patients who are at high risk for CEA surgery and ≥ 80 years of age?

## B. Discussion of evidence reviewed

### 1. Literature Search

Because this is a reconsideration, CMS focused on reported studies since the prior decision and searched PubMed from 2005 to present. General keywords included carotid artery and stenting or stent. Studies must have presented original data, examined primary health outcomes and been published in peer-reviewed English language journals. Abstracts were excluded.

**2. External technology assessments and clinical reviews**

Cremonesi A, Setacci C, Bignamini A, et al. Carotid artery stenting. First Consensus document of the ICCS-SPREAD Joint Committee. Stroke 2006;37:2400-2409.

Cremonesi and colleagues presented an evidence-based guideline and consensus document on CAS for the Italian Consensus Carotid Stenting (ICCS)/SPREAD [Stroke Prevention and Educational Awareness Diffusion] group [a multidisciplinary association representing > 30 scientific societies and patient organizations in the field of cardiovascular disease, which, during the last 7 years, has released 4 editions of evidence-based guidelines for stroke prevention and treatment (http://www.spread.it)]. The consensus document addressed "the main issues related to methodology, definition of symptomatic and asymptomatic carotid stenosis, indication and procedures for carotid artery stenting, including the use of devices for preventing procedural embolic complications." In addition, the group addressed "credentials and competency for physician qualifications to perform vascular angioplasty and stent placement, including training, acceptable complication rates and certification."

The report states:

- "Given that current evidence is still insufficient, endarterectomy should not be systematically replaced with endovascular procedures for the elective correction of carotid stenosis." Recommendation 3: Grade A (At least 1 meta-analysis, systematic review, or RCT rated as 1++ and directly applicable to the target population; or systematic review of RCTs or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results).
- "CAS, if performed with adequate procedural quality levels, should be used instead of endarterectomy in the presence of severe vascular or cardiac comorbidities or specific conditions." Recommendation 4: Grade B (A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or extrapolated evidence from studies rated as 1++ or 1+).

The group defined high risk as the following:
"Conventionally, high risk for surgery is suspected in the presence of:
Specific conditions:

- contralateral laryngeal nerve palsy;
- radiation therapy to the neck;
- previous CEA with recurrent restenosis;
- high cervical internal carotid/below the clavicle common carotid lesions;
- severe tandem lesions;
- age > 80 years;
- severe pulmonary disease.

Severe vascular and cardiac comorbidities:

- congestive heart failure (New York Heart Association class III/IV) and/or known severe left ventricular dysfunction;
- open heart surgery needed within 6 weeks;
- recent myocardial infarction (> 24 hours and < 4 weeks);
- unstable angina (Canadian Cardiovascular Society class III/IV);
- contralateral carotid occlusion.

This definition of high risk, however, is not evidence based and is not universally shared."

For physician training, the group states:
"Once the basic skill for catheter-based intervention has been achieved by the already-active interventionist, the minimum recommended training to achieve competence is as follows:

- At least 150 procedures of supra-aortic vessel engagement (during diagnostic as well as interventional procedures) within 2 years, of which at least 100 as the primary operator;
- At least 75 carotid stenting procedures, of which at least 50 as the primary operator, within a 2-year fellowship. Recommendation 10: Grade GPP (Recommended best practice based on the clinical experience of the guideline development group, without research evidence);
- The minimum requirement to maintain technical skill (competence) is the number of 50 carotid stenting procedures performed and documented by each primary operator per year. Recommendation 11: Grade GPP."

**3. Internal technology assessments**

Since this is a reconsideration of the 2005 policy, we focused our search on studies published or presented from the time of the prior decision. Two randomized trials, 5 case series or registry studies, 2 presentations, and 1 evidence based clinical guideline were considered.

Chaer RA, Derubertis BG, Trocciola SM, et al. Safety and efficacy of carotid angioplasty and stenting in high risk patients. American Surgeon 2006;72:694-699.

Chaer and colleagues reported the results of an observation study (vascular registry) of 545 patient who underwent CEA and 148 patients who underwent CAS. Patients were treated from 1997 to 2005 at 1 institution (outside US). All patients were considered at high risk for surgical intervention. Inclusion criteria were not specified. The main endpoint was cumulative death, stroke and MI within 30 days after the procedure, or death or ipsilateral stroke for the follow-up period. Mean age was 71 years for the CEA patients and 75 for the CAS patients. Women comprised 68% of the CEA group and 61% of the CAS group. Mean stenosis was 78% in the CEA group and 87% in the CAS group. Mean follow-up was 23 months and 18 months, respectively. The 30-day endpoint was 4% for the CEA group and 3.4% for the CAS group. All patients who underwent CAS received clopidogrel for at least 30 days. The authors concluded that "CAS is equivalent to CEA in safety and efficacy, even when performed in patients who may be at increased surgical risk" (Chaer et al., 2006).

Gray WA, Hopkins LN, Yadav S, et al. Protected carotid stenting in high-surgical-risk patients: the ARCHeR results. J Vasc Surg 2006;44:258-269.

Gray and colleagues reported the results of ARCHeR (Acculink for Revascularization of Carotids in High-Risk Patients) which was comprised of 3 case series studies of 581 patients who underwent CAS. Patients were treated from 2000 to 2003 at 48 centers (US and outside). All patients were considered at high risk for surgery. Eligibility criteria included symptomatic stenosis ≥ 50% or asymptomatic stenosis ≥ 80% by angiography. The primary endpoint was a composite of periprocedural (≤ 30 days) death, stroke, and MI, plus ipsilateral stroke between days 31 and 365. Cumulative results were presented. Mean age was 70 years. Men comprised 67% of the patients. Most patients had asymptomatic stenosis (76%). The overall 30-day stroke, death, and MI rate was 8.3%, with 13.0% for symptomatic patients and 6.8% for asymptomatic patients. The authors concluded: "The ARCHeR results demonstrate that extracranial carotid artery stenting with embolic filter protection is not inferior to historical results of endarterectomy and suggest that carotid artery stenting is a safe, durable, and effective alternative in high-surgical-risk patients" (Gray et al., 2006). The results of the ARCHeR studies were presented earlier and considered in our prior decision.

Halabi M, Gruberg L, Pitchersky S, et al. Carotid artery stenting in surgical high-risk patients. Catheterization and Cardiovascular Interventions 2006;67:513-518.

Halabi and colleagues reported the results of a case series of 116 patients who underwent CAS. Patients were treated from 1998 to 2004 at 1 facility (outside US). All patients were considered at high risk for surgery. Both symptomatic (≥ 60% stenosis) and asymptomatic (≥ 70% stenosis) patients were included but results were not presented by subgroups. Endpoints included death and stroke during inpatient stay, at 30 days and 12 months. Mean age was 71 years. Men comprised 62%. During the inpatient stay, there were 3 death and strokes (2.6%). At 30 days, there were 3 death and strokes (2.8%). At 1 year, there were 4 death and stokes (7.8%). The inpatient events occurred in patients that did not receive distal protection (3/67). The authors concluded: "These results support the use of carotid artery angioplasty and stenting in high-risk patients with significant primary or secondary carotid artery stenosis" (Halabi et al., 2006).

Mas JL, Chatellier G, Beyssen B, et al. Endarterectomy versus stenting in patients with symptomatic severe carotid stenosis. N Engl J Med 2006;355:1660-1671.

Mas and colleagues reported the results of a randomized noninferiority trial, the Endarterectomy versus Angioplasty in Patients with Symptomatic Severe Carotid Stenosis (EVA-3S). The primary endpoint was incidence of death and stroke with 30 days of intervention. Inclusion criteria included TIA (transient ischemic attack) or nondisabling stroke with 120 days of enrollment, and stenosis 60-99% as determined by NASCET (North American Symptomatic Carotid Endarterectomy Trial) criteria. There was no enrollment restriction based on surgical risk so patients who were at low or high risk for CEA were included in the study. Exclusion criteria included disabling stroke (modified Rankin score ≥ 3), severe tandem lesions, and life expectancy < 2 years. The trial started in November 2000 and was conducted in 30 centers (France). By September 2005, 527 patients were randomly assigned to CEA (n=262; 257 completed, 0 failed) or CAS (n=265; 247 completed, 13 failed). Mean age was 70 years. Men comprised 75% of the patients. Most patients (72%) had stenosis ≥ 80%. At the planned data analysis in September 2005, the safety committee recommended stopping enrollment. The 30-day incidence of any stroke or death was 3.9% in the CEA group and 9.6% in the CAS group, with a relative risk of 2.5 (95% confidence intervals = 1.2 to 5.1). Patients who underwent CAS without distal protection had a higher incidence of stroke or death compared to patients who underwent CAS with distal protection (25% versus 7.9%; p-value=0.03). The trial was stopped early for reasons of both "safety and futility" as noted. The authors concluded that in "patients with symptomatic carotid stenosis of 60% or more, the rates of death and stroke at 1 and 6 months were lower with endarterectomy than with stenting" (Mas et al., 2006).

Several correspondences (Bonvini and Righini, Hamon and Riddell, Maree and Rosenfield) were published in response to the EVA-3S trial report. The authors mentioned that physician experience and use of distal embolic protection devices may have influenced the trial outcomes. Mas and colleagues replied with additional analyses that the 30-day risk of stroke or death did not differ significantly by physician CAS experience and that the 30-day risk of stroke or death was significantly higher in the CAS group compared to the CEA group when patients who did not receive distal embolic protection were excluded from the analysis (Mas et al., 2006).

Park B, Mavanur A, Dahn M, Menzoian J. Clinical outcomes and cost comparison of carotid artery angioplasty with stenting versus carotid endarterectomy. J Vasc Surg 2006;44:270-276.

Park and colleagues reported the results of a case series of 94 patients who underwent CEA (n=48) and CAS (n=46). Patients were treated from 2003 to 2005 at 1 institution (US). Eligibility criteria included asymptomatic stenosis ≥ 80% or symptomatic stenosis ≥ 50%, as measured by duplex ultrasound. Patient data were collected retrospectively. Endpoints included technical success, procedure related mortality, major adverse events, and costs. Mean age was 71 years. Men comprised 53% of the study population. There were no significant differences in technical success, 30-day mortality and stroke rates, and MI rate. The authors concluded: "CAS with neuroprotection was associated with clinical outcomes equivalent to those with CEA but had higher total hospital costs" (Park et al., 2006).

Safian RD, Bresnahan JF, Jaff MR, et al. Protected carotid stenting in high-risk patients with severe carotid artery stenosis. J Am Coll Cardiol 2006;47:2384-2389.

Safian and colleagues reported the results of a multicenter registry of 419 patients who underwent CAS [Carotid Revascularization with ev3 Arterial Technology Evolution (CREATE)]. The primary endpoint was a composite of death, ipsilateral stroke, procedure related contralateral stroke, and MI. Patients were treated in 2004 at 32 participating centers. All patients were considered high risk. Eligibility criteria included symptomatic stenosis ≥ 50% and asymptomatic stenosis ≥ 70%. Mean age was 74 years. Men comprised 61% of the study population. Most patients had asymptomatic stenosis (83%). The primary endpoint occurred in 26 patients (6.2%). There were 8 deaths, 14 nonfatal strokes, and 4 MIs. The authors concluded: "For some patients with severe carotid stenosis and high-risk features for carotid endarterectomy, carotid artery stenting with distal embolic protection is a reasonable alternative for revascularization" (Safian et al., 2006).

The SPACE Collaborative Group. 30 day results from the SPACE trial of stent-protected angioplasty versus carotid endarterectomy in symptomatic patients: a randomized non-inferiority trial. Lancet 2006;368:1239-1247.

The SPACE (Stent-Protected Percutaneous Angioplasty of the Carotid vs Endarterectomy) Collaborative Group reported the results of a randomized non-inferiority trial that compared CEA to CAS in patients with severe symptomatic carotid artery stenosis. The primary endpoint was ipsilateral stroke or death of any cause up to 30 days after treatment. Eligibility criteria included neurological or ocular symptoms such as amaurois fugaz, TIA, stroke in the previous 180 days and severe stenosis ≥ 70% by duplex ultrasound, which corresponds to ≥ 50% according to NASCET criteria. There was no enrollment restriction based on surgical risk so patients who were at low or high risk for CEA were included in the study. The use of a distal embolic protection device was optional. From 2001 to 2006, 1200 patients were randomly assigned to CAS (n=605; 599 followed up and included in the analysis) or CEA (n=595; 584 followed up and included in the analysis). Patients were treated at 35 trial centers in Germany, Austria and Switzerland. Mean age was 68 years. Men comprised 72% of the study population. In the CAS group, embolic protection devices were used in 27% (151/567) of the procedures. At 30 days post procedure, the primary endpoint occurred in 41 (6.8%) patients in the CAS group compared to 37 (6.3%) in the CEA group (absolute difference = 0.51; 90% CI = -1.89 to 2.91). The authors concluded: "SPACE failed to prove non-inferiority of carotid-artery stenting compared to carotid endarterectomy for the periprocedural complication rate. The results of this trial do not justify the widespread use in the short-term of carotid-artery stenting for treatment of carotid-artery stenoses" (SPACE Group, 2006).

Stanziale SF, Marone LK, Boules TN, et al. Carotid artery stenting in octogenarians is associated with increased adverse outcomes. J Vasc Surg 2006;43:297-304.

Stanziale and colleagues reported the results of analysis of a prospective registry of carotid stent patients "to determine if octogenarian status affects periprocedural as well as 1-year outcomes." From 1996 to 2004, the registry included 384 patients, including 260 from 10 trials, that were treated at 1 institution (US). Outcomes included periprocedural stroke, TIA, MI and death. There were 87 patients that were ≥ 80 years and 295 patients < 80 years. The investigators found that "All adverse outcomes were significantly higher in octogenarians compared with younger patients: 30-day stroke rate, 8.0% vs 2.7% (P = .02); 30-day stroke, myocardial infarction, or death, 9.2% vs 3.4% (P = .02)." The authors concluded: "Octogenarians undergoing carotid artery stenting are at higher risk than nonoctogenarians for periprocedural complications, including neurologic events and death. Major event-free survival at 1 year is also significantly better in nonoctogenarians. These risks should be weighed when considering carotid stenting in elderly patients" (Stanziale et al., 2006).

**Post Approval Studies**

Guidant Corporation. Carotid RX ACCULINK® / ACCUNET Post-Approval Trial to Uncover Unanticipated or Rare Events (CAPTURE), 2006.

Gray WA, Yadav JS, Verta P, et al. The CAPTURE registry: Results of carotid stenting with embolic protection in the post approval setting. Catheterization and Cardiovascular Interventions 2006; Published Online 12/14/2006 at: http://www3.interscience.wiley.com/cgi-bin/fulltext/113517832/HTMLSTARTW?CRETRY=1&SRETRY=0.

In December 2006, Guidant Corporation presented the results of CAPTURE to CMS. CAPTURE was a registry study that was mandated by the FDA as part of the PMA approval granted in September 2004. The purpose of CAPTURE was to collect data on carotid artery stenting in patients at high risk for surgery using the Guidant carotid artery stent (ACCULINK) and embolic protection device (ACCUNET), when used by a broad group of physicians under commercial use conditions. The primary endpoint was a composite of death, stroke and MI within 30 days post-index procedure. Eligibility criteria included indications according to the FDA labeling, specifically symptomatic stenosis ≥ 50% and asymptomatic stenosis ≥ 80%. At the time of the report, there were 3500 patients enrolled in the registry through 140 study sites. Mean age was 73 years with 24% of patients ≥ 80 years. Men comprised 61% of the registry population. Most patients had asymptomatic stenosis (86%). The primary endpoint of all stroke, death and MI occurred in 6.3% of the patients. The endpoint was 13.0% for symptomatic patients and 6.8% for asymptomatic patients. There were no statistically significant differences reported for physician experience levels. Patients ≥ 80 years of age had significantly higher rates of death, strokes and the composite events (9.4%) compared to patients < 80 years (5.3%). Many of the CAPTURE findings that were presented to CMS were subsequently published online.

Cordis Corporation. Carotid Artery Stenting with Embolic Protection in Patients at High Surgical Risk for Carotid Endarterectomy, 2006.

In March 2006, Cordis Corporation presented the interim results of CASES-PMS (Carotid Artery Stenting Education System Post-Market Study) to CMS. CASES-PMS was a registry study to assess safety and efficacy of CAS with distal protection in high surgical risk patients using the Cordis carotid stent (PRECISE) and embolic protection device (ANGIOGUARD), when performed by physicians outside the setting of a controlled trial with various levels of CAS experience. The primary endpoint was a 30 day composite of all death, all stroke and MI. Eligibility criteria included symptomatic stenosis ≥ 50% and asymptomatic stenosis ≥ 80%. At the time of the report, there were 1479 patients enrolled in the registry through 73 participating centers. Most patients (78%; 1157/1479) had asymptomatic stenoses. The primary endpoint occurred in 4.8% of enrolled patients. It was 5.9% for symptomatic patients and 4.5% for asymptomatic patients. There were no significant differences by physician experience (number of procedures performed).

Cordis Corporation. Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy (SAPPHIRE) 3 Year Results, 2006.

In March 2006, Cordis Corporation presented the 3 year follow-up results for the SAPPHIRE (Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy) trial which originally studied 334 patients. Similar to the published findings (Yadav et al., 2004), the CAS with embolic protection was not inferior to CEA. The 3 year cumulative percentage of death, stroke and MI was 26.2% for CAS patients and 30.3% for CEA patients (p=0.273). For the 3 year follow-up data, the number of patients included in the analysis for each group was not reported. The number of patients lost to follow-up was also not available.

**4. MCAC**

Not applicable.

**5. Guidelines**

Not applicable.

**6. Professional Society Position Statements**

Not applicable.

**7. Expert Opinion**

Not applicable.

**8. Public Comments**

CMS received 119 public comments during the initial 30-day public comment period. The majority of commenters support an expansion of coverage for CAS consistent with the reconsideration request. A large number of citations are referenced by the commenters and a complete list is available in Appendix B of this document.

**Comments with Evidence**
***Expand Coverage***
*CASES-PMS, ACC 2006.*
Four (4) commenters state that the results from Cordis Corporation's CASES-PMS study demonstrate the safety and effectiveness of CAS with embolic protection and, therefore, support the requested expansion of Medicare coverage which would provide coverage for the FDA-approved indications for CAS.

*Kakkos SK, et al., 2005.*
One commenter states that these results, which demonstrated that patients with medical comorbidities had an increased natural history of stroke, question the American Heart Association < 3% revascularization risk benchmark for assessing the role of CAS in high surgical risk patients with comorbidities. One commenter affirms that this study supports Medicare coverage of the FDA-approved indications for CAS.

*Gray WA, et al. for the ARCHeR Trial Collaborators, 2006.*

Three (3) commenters cite the ARCHeR trial results to contend that the FDA-approved indications for CAS should be covered by Medicare. Two (2) commenters state that these results show that CAS is better than or at least equal to CEA in preventing stroke. One commenter states that the ARCHeR results demonstrate the durability of CAS.

*White CJ, et al. BEACH Trial 30 Day Results 2006; BEACH: unpublished data, 2005.*
Five (5) commenters cite results from the BEACH (Boston Scientific/EPI: A Carotid Stenting Trial for High Risk Surgical Patients) trial to support their contention that Medicare should expand coverage for CAS to the FDA-approved labeled indications for use.

*CAPTURE, ACC 2006.*
Five (5) commenters assert that data from the CAPTURE study supports expanding coverage to symptomatic high risk patients with 50-70% stenosis and asymptomatic high risk patients with ≥80% stenosis. One commenter states that an expansion of coverage is appropriate because CAPTURE results demonstrate the safety of carotid stenting with embolic protection devices and another commenter states that the evidence supports coverage for asymptomatic high risk patients.

*Yadav JS, et al., 2004; SAPPHIRE 2002 unpublished data, 2003.*
Five (5) commenters state that the SAPPHIRE results demonstrate the durability of CAS and show CAS to be at least as effective in preventing stroke as CEA. Two (2) commenters attest that this study supports coverage of the FDA-approved indications for CAS.

*SECURITY unpublished data, TCT 2003.*
Three (3) commenters contend that the SECURITY (Registry Study to Evaluate the Neuroshield Bare Wire Cerebral Protection System and X-Act Stent in Patients at High Risk for Carotid Endarterectomy) results support coverage of FDA-approved indications. One commenter states that data from SECURITY shows CAS to be durable and at least as effective in preventing stroke as CEA.

*Safian, et al., 2006.*
One commenter supports expanded coverage by citing this article, which demonstrates that CAS with embolic protection is a reasonable revascularization alternative.

*42 CFR Parts 409, 410, 412, et al.*
One commenter cites this CMS regulation to note that CMS has already recognized CAS as a safe and effective treatment option for high risk patients in payment and coverage policies so coverage should be extended to all FDA-approved high risk indications.

*MAVErIC (The Evaluation of The Medtronic AVE Self-Expanding Carotid Stent System with Distal Protection in the Treatment of Carotid Stenosis) unpublished data, TCT 2004; CABERNET (Carotid Artery Revascularization Using the Boston Scientific FilterWire EX/EZ and the EndoTex NexStent) unpublished data, ISC 2005.*
Two (2) commenters cite data from these studies, which indicate that CAS is durable and at least as effective in preventing stroke as CEA, to support expanding coverage.

*Alamowich S, et al., 2005.*
One commenter states that the results discussed in this article show CAS to be durable and equal to or more effective than CEA in preventing stroke.

*Brooks WH, et al., 2004; Bush RL, et al., 2005; Derubertis BG, et al., 2006; Park B, et al., 2006; Yen MH, et al., 2005.*
One commenter affirms that these studies support Medicare coverage of the FDA-approved indications for CAS.

*Goldstein LB, et al., 1994; Sundt, et al., 1975.*
One commenter cites these historical controls and contends that they compare favorably to ARCHeR and SECURITY which support expanded coverage.

***Maintain Current Coverage Policy***
*Cronenwett J, 1997.*
One commenter references his own article in asserting that CEA in patients age 70 and older is not cost-effective because these patients do not live long enough for the future benefit to outweigh the initial cost. He also states that none of the CAS studies have demonstrated a stroke risk low enough to be cost-effective for Medicare beneficiaries.

*Kresowik TF, et al., 2001.*
One commenter cites the conclusions of this report which state that the limits for allowable surgical complications are often exceeded for asymptomatic patients.

*Jordan WD, et al., 2002; Gasoaris AP, et al., 2003.*

Three (3) commenters cite these articles to note that studies have yet to conclusively identify which patient populations are at high risk for CEA and thus appropriate candidates for CAS.

*Mas, et al., 2006; Mas JL. Cerebrovasc Dis., 2005.*
Three (3) commenters cite the lower stroke and death rates reported in the CEA group as opposed to the stenting group to refute the request for coverage expansion.

*ACAS (Asymptomatic Carotid Atherosclerosis Study).*
One commenter cites this study stating that since no studies have shown a complication rate < 3% then there is no reason to conclude that patients benefit from CAS.

*CAPTURE, ACC 2006.*
One commenter contends that higher complication rates were seen in CAS patients as compared with CEA patients and one commenter states that CAPTURE results show an unacceptably high rate of stroke, death, and myocardial infarction (SDMI) as compared to other CEA studies.

*Yadav et al., 2004; SAPPHIRE 2002 unpublished data, 2003.*
One commenter asserts that the SAPPHIRE results are not acceptable for stroke prevention and that the increased rates of stroke are not due to carotid plaque.

*Alamowich, et al., 2005.*
One commenter contends that the 50-60% stenosis group showed no benefit for CEA in women and that there is a difference in benefit of CEA in men and women due to different risks of stroke. Since no benefit was demonstrated in women, only men should receive revascularization until more data is collected demonstrating benefit in women.

*Inzitari, et al., 2000.*
One commenter refutes the need for coverage of CAS by citing data discussed in this article which shows that increased stenosis in asymptomatic patients does not necessarily cause an increase in the risk of stroke. This commenter also notes that the correction of carotid stenosis by either CAS or CEA only reduces strokes by 1% per year and half the causes for stroke remain with patients.

***Coverage of Octogenarians***
*Goldstein LB, et al., 1998; Miller MT, et al., 2005; Teso D, et al., 2005.*
Three (3) commenters support withdrawing coverage of CAS in octogenarians due to the lower stroke and death rates reported in these studies following CEA as opposed to CAS.

*Halliday A, et al., 2004.*
One commenter cites this study to conclude that since benefits only exceed risks when appropriate hazards remain low and interventions for asymptomatic stroke patients are only beneficial for the long term, there is no benefit and should not be coverage for patients > 75 years old.

*Hobson RW 2nd, et al., 2004.*
Two (2) commenters contend that octogenarians should not receive coverage for CAS due to the high stroke and death rate observed in these results.

*The SPACE Collaborative Group, 2006.*
One commenter asserts that these results indicate that CAS in octogenarians should not be covered by Medicare due to the high stroke and death rates reported.

*Stanziale SF, et al. 2006.*
One commenter cites this article to support the contention that CAS should not be covered for patients age 80 and above due to poor outcomes.

***Use of Embolic Protection***
*Pinero P, et al.; Hong GR, et al.*
One commenter cites these studies which demonstrated the occurrence of more embolic events with CAS as compared to CEA to support the use of embolic protection devices.

*Sztriha LK, et al., 2004.*
One commenter cites this article which concludes that "carotid artery stenting without protection devices appears to be safe" to support the contention that coverage of CAS without embolic protection should be granted by Medicare.

***In the Opinion of a Surgeon***

*EVA-3S Trial.*

One commenter cites the EVA-3S trial, which shows CEA to be the standard treatment for stroke prevention, to contend that all patients should undergo a surgical evaluation to be determined an appropriate patient for CAS.

*The SPACE Collaborative Group, 2006.*

One commenter attests that this study shows that CEA is the standard treatment of carotid artery stenosis so potential CAS patients should be required to be evaluated by a surgeon.

***Additional Evidence***

*Cochrane Database Systematic Review, 2005.*

One commenter states that this analysis shows that CEA has shown marginal benefit for patients with asymptomatic carotid stenosis at low risk for surgery.

*Barnett HJM, et al., 1998.*

One commenter asserts that in basing the current coverage limitations on data from patients from this study, CMS applied data on one procedure in one patient population to a different procedure performed on a different patient population. This study showed a moderate reduction of risk of stroke in patients with moderate symptomatic carotid stenosis who underwent CEA. Using this as a rational for limiting coverage was inappropriate because patients who receive CEA are often not at high risk as patients receiving CAS must be. The commenter states that CMS must compare similar populations in making coverage decision.

*Barnett HJM, et al., 2003.*

One commenter references this selection to note that the possibility of procedural risk outweighing procedural benefit is under appreciated.

*Barnett HJM, 2004.*

One commenter cites this analysis of the ACE Trial to note that as the intervention benefit decreases and the complication rate increases, the hazard of the intervention becomes more clinically relevant. ACE asymptomatic patients experienced no benefit for 4 years post CEA during which more strokes may have occurred, which illustrates the importance of weighing procedural risk and potential benefits.

*Biller J, et al., 1998.*

One commenter cites these patient selection guidelines which state that for symptomatic women, there is no benefit from CEA for stenosis < 70% or for interventions performed more than two weeks after the sentinel event. For symptomatic males with >70% stenosis, a benefit exists with an intervention performed < 12 weeks from the sentinel event.

*Chambers BR, Norris JW, 1986.*
One commenter contends that recent and current registries wrongly justify their studies with the erroneous conclusion, due to outdated equipment, from this study that increased stenosis validates interventions for asymptomatic patients.

*Liberato B, et al., Presented at American Academy of Neurology Annual Meeting, 2004.*
One commenter cited this study in cautioning Medicare that the risk of treatment must not be worse than the condition being treated. This commenter notes that this data shows that most strokes are not caused by carotid stenosis and therefore any revascularization will be used on a limited number of patients and thus cause little impact in overall stroke morbidity and mortality.

*Longstreth WT Jr, et al., 1998.*
One commenter references this study to show that most strokes are not caused by carotid stenosis. This was demonstrated in long term patient follow up where a low correlation between high stenosis and long term stroke risk was illustrated. This commenter cautions Medicare to consider whether overall stroke incidence is reduced with CAS.

*Rothwell PM, et al., 2004.*
One commenter cites this study to state that no women benefited from CEA in the NASCET 50-60% stenosis group and the entire ACAS study, or in the > 70% stenosis group if treated > 2 weeks post episode. Males with 50-69% stenosis experienced marginal benefits from interventions performed 2 weeks post event.

*Collins R, et al., 2004.*
Two (2) commenters attest that this study confirms that strokes are dependent on the severity of presenting atherosclerosis and comorbidities. Since the study was of normal risk patients, the resulting event rates cannot be applied to the Medicare population with comorbidities.

*Chaturvedi S, et al., 2005.*
One commenter cites this review to contend that had the ACAS and ACST studies examined identical endpoints, the absolute benefit of CEA would have been reduced and thus question the benefit of revascularization in subpopulations.

*Sacks D, Connors JJ 3rd, 2004.*
One commenter references this citation to assert that CAS must fulfill the same benefits as CEA in order to be beneficial and thus appropriate for Medicare coverage.

*Gorelick PB, 1999.*
One commenter cites this article to contend that the benefits of CEA in patients with symptomatic carotid stenosis are questionable and sensitive in nature.

*Gray WA, et al. for the ARCHeR Trial Collaborators, 2006.*
Four (4) commenters state that the ARCHeR results were unacceptable, with the worst outcomes in asymptomatic patients. One commenter notes that patients might be at high risk for stroke due to factors not examined.

*Halm EA, et al., 2005; Matsen SL, et al., 2006 in press; Stoner MC, et al., 2006.*
Three (3) commenters reference these studies to identify how the safety of CEA is generally accepted over a broad range of surgical practice.

*The SPACE Collaborative Group, 2006.*
Three (3) commenters state that the SPACE trial failed to prove non-inferiority of CAS vs. CEA for procedural complication rates nor did the study look at high-risk patients so this trial is not applicable to this national coverage analysis (NCA). Another commenter notes that patients in this study were selected because they were at high risk for surgery; however, they may have been at high risk for stroke due to other factors which were not discussed. One commenter states that the SPACE results demonstrate that CAS is not an acceptable treatment for stroke prevention, especially in asymptomatic patients at a lower risk for stroke.

*SECURITY unpublished data, TCT 2003.*
Three (3) commenters note that the results of this study do not differentiate between asymptomatic and symptomatic patients so they cannot be interpreted and utilized in making this coverage decision.

*The SPARCL (Stroke Prevention by Aggressive Reduction in Cholesterol Levels) Study.*

One commenter notes that data on carotid artery disease is difficult to extrapolate from this study and therefore cannot be used to determine coverage for CAS. Another commenter states that it was unlikely that patients in this study had significant carotid disease and the results do not support using medical therapy as a substitute for revascularization.

**Comments without Evidence**

***Expand Coverage***

One hundred and two (102) commenters support expanding the current CAS policy. Fifty seven (57) request coverage for symptomatic patients at high risk for CEA with ≥ 50% stenosis and asymptomatic patients at high risk for CEA with ≥ 80% stenosis and nine (9) commenters support a general expansion of coverage. Four (4) commenters request coverage for high risk, asymptomatic patients and six (6) commenters request coverage for all symptomatic patients. Nine (9) commenters state that CAS should be covered for all patients eligible for coverage of CEA. One commenter asserts that symptomatic patients with > 50% stenosis should have a revascularization option. One commenter requests coverage for low risk patients.

Ten (10) commenters support expanded coverage because CAS is at least equally effective in preventing stroke as CEA, while three (3) commenters state that coverage should be expanded because CAS is safe and effective. One commenter states that additional coverage would alleviate ethical dilemmas encountered in research, while another commenter contends that asymptomatic high risk patients should only be covered in clinical trials. One commenter asserts that since large scale randomized controlled trials (RCTs) comparing CEA and CAS would be impossible ethically and from an enrollment standpoint, an expansion of coverage should not be delayed until RCTs have been completed. One commenter states that CAS should be covered as an outpatient procedure.

One commenter suggests rather than requiring patients to meet "high risk" criteria, independent angiographic auditing should be required post procedure with significant consequences for procedures found to have been performed on inappropriate patients.

One commenter states that continuing the noncoverage policy for asymptomatic patients with high degrees of stenosis is contrary to research findings. One commenter states that coverage should be dictated by Society for Vascular Surgery (SVS) guidelines and Society for Cardiovascular Angiography and Interventions (SCAI) guidelines. One commenter contends that the current policy promotes CEA which is riskier and more invasive, therefore coverage should be expanded.

***Maintain/Limit Coverage***

Twelve (12) commenters state that the current policy should not be changed. Eight (8) commenters contend that more evidence is needed to justify an expansion of coverage and two (2) commenters state that no new level 1 evidence is available and coverage should not be expanded until data from the CREST (Carotid Revascularization Endarterectomy vs. Stent Trial) study is available. Five (5) commenters assert that no studies show CAS to be equal or superior to CEA and three (3) commenters contend that CEA is the gold standard and coverage should not be expanded until indisputable evidence supporting CAS is available. One commenter notes that since March 2005, there is no new data to support an expansion of coverage.

Two (2) commenters question the benefit derived from CEA and thus the appropriateness of coverage in different populations for men and women.

One commenter states that an expansion of coverage for CAS would impede clinical trials like CREST and stop the use of CEA. Another commenter contends that additional coverage would limit patient enrollment in clinical trials and prevent development of level 1 data. One commenter notes that no benefit has been shown for patients with 50-69% stenosis thus this group should not be covered. One commenter asserts that studies have shown the risk of ipsilateral stroke in asymptomatic patients to be variably related to stenosis and comorbidities.

One commenter asserts that coverage for patients age 80 and older should be repealed.

***In the Opinion of a Surgeon***

Thirteen (13) commenters state that the high risk for CEA determination must be made by a surgeon. One commenter contends that multiple specialty review is necessary to eliminate self referral in medical imaging and one commenter suggests that a neutral physician be required to evaluate patients to make the high risk determination. One commenter asserts that collaborative decision making is necessary for symptomatic patients with > 50% stenosis with 1) severe pulmonary disease; 2) high cervical ICA lesions or CCA lesions below the clavicle; 3) severe tandem lesions; 4) age > 80; 5) congestive heart failure (CHF) (III, IV) or known severe left ventricular ejection fraction (LVEF) < 30%; 6) open heart surgery within 6 weeks; 7) recent MI (> 24 hours, < 4 weeks); and 8) unstable angina (CCS class III/IV). Another commenter states that symptomatic patients with ≥ 50% stenosis with 1) contralateral carotid occlusion; 2) contralateral laryngeal nerve palsy; 3) radiation therapy to the neck; and 4) previous CEA with restenosis. One commenter suggests allowing co-surgeon codes to "level the playing field" between surgeons and interventionalists while ensuring patients are appropriately evaluated and informed of their options.

Fifteen (15) commenters state that the high risk determination should not be required to be made by a surgeon. Two (2) commenters contend that requiring a surgical evaluation is inappropriate due to the subsequent conflict of interest of the evaluating surgeon. One commenter supports removing the language because no evidence supports this requirement and the language is confusing.

***Facility Certification and Oversight***

Six (6) commenters support the implementation of stringent oversight and screening processes for hospitals and physicians and four (4) commenters support requirements for facility accreditation. Five (5) commenters encourage CMS to develop a program to ensure that only qualified physicians perform CAS while one commenter states that physicians should not be required to meet additional training requirements. Two (2) commenters state that a professional society or organization should be recognized as a certifying body, one commenter asserts that facilities should be required to use national registries, and one commenter states that the SVS registry should be used.

***High Risk for CEA***

One commenter states that patients should be able to choose between CAS and CEA if their anatomy is favorable regardless of whether or not they are at high risk for CEA. Two (2) commenters recommend specifically defining "high risk" criteria and strictly limiting CAS to patients meeting these criteria. Another commenter contends that "high risk" criteria should be defined as 1) contralateral carotid occlusion; 2) previous CEA with recurrent stenosis; 3) radial neck dissection; 4) surgically inaccessible cervical lesion, above C2; 5) common carotid artery lesion below clavicle; 6) contralateral vocal cord palsy; and 7) presence of tracheostomy stoma.

***Use of Embolic Protection***

Two (2) commenters assert that coverage should not be contingent on the use of embolic protection devices and one commenter contends that CAS should be covered without the use of an embolic protection device when 1) a reasonable attempt is made and documented; or 2) the risks outweigh the benefits.

***CMS Evidence Review***

One commenter contends that CMS based the previous CAS decision on a flawed comparison of safety and efficacy data and that new decisions must be determined through comparisons of like patient populations. They state that CMS should evaluate safety and effectiveness based on data specific to the patient populations under consideration.

**VIII. CMS Analysis**

National coverage determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII of the Social Security Act §1869(f)(1)(B). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Moreover, with limited exceptions, the expenses incurred for items or services must be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member" (§ 1862(a)(1)(A)).

**● Is the evidence sufficient to conclude that PTA with carotid artery stenting improves health outcomes for patients who are at high risk for CEA surgery with symptomatic carotid artery stenosis ≥ 50%?**

In the prior decision, CMS provided coverage for patients who are at high risk for CEA surgery with symptomatic carotid artery stenosis ≥ 70% and patients with symptomatic carotid artery stenosis 50-70% in clinical trials or post-approval studies. Since then, 2 randomized clinical trials (EVA-3S, SPACE) and several reports based on registry data (Safian, CAPTURE, CASES-PMS) were published and provide evidence on this population. The SPACE and EVA-3S trials compared CAS to CEA in patients with symptomatic stenosis ≥ 50% and ≥ 60%, respectively, by NASCET criteria. However, they did not specifically limit inclusion to patients who were at high surgical risk. Both SPACE and EVA-3S were stopped early and failed to show that CAS was not inferior to CEA. When considering these trials, a factor that may help explain why the results were different from the SAPPHIRE trial that provided much of the reasons for coverage is the use of distal embolic protection devices. In the SPACE trial, the majority of patients (416/567; 73%) were treated without using an embolic protection device. In the EVA-3S trial, the majority of patients (227/247; 92%) did receive a device but, for those patients who did not, there was a higher incidence of stroke or death at 30 days. While the use of distal embolic protection devices may help explain the outcomes, the results of these trials do not provide evidence to expand coverage of CAS to patients with symptomatic stenosis ≥ 50% and < 70%. The study reports by Chaer, Halabiand and Park did not present results by symptom subgroups. The post-approval studies CAPTURE and CASES-PMS did not show significant differences overall between CAS and CEA, but both studies showed that symptomatic patients had higher 30-day adverse outcomes compared to asymptomatic patients.

For symptomatic stenosis, the strength of the evidence, since our prior decisions, lies with the randomized trials, SPACE and EVA-3S, which failed to show noninferiority of CAS compared to CEA. Not only do these trials provide insufficient evidence for expansion of coverage, but they also raise questions about CAS for all patients with severe symptomatic carotid artery stenosis, particularly the results of EVA-3S which showed a 5.6% higher incidence of stroke and death. Since these studies did not present results by degree of stenosis, it is not possible to determine whether symptomatic patients with stenosis 50%-70% experienced better or worse outcomes than patients with stenosis ≥ 70%. Thus the evidence based on the overall trial results is insufficient to support expanding coverage to symptomatic patients with stenosis 50%-70%. This patient population will remain covered in FDA-approved Category B IDE clinical trials and FDA-approved post approval studies as established in previous decisions.

The EVA-3S and SPACE trials did not limit inclusion to only patients at high risk for CEA surgery. It is unclear what, if any, influence this had on the outcomes, but it would be reasonable to believe that patients at low risk would have better outcomes than patients at high risk. These trials do support the use of distal embolic protection devices and showed poor patient outcomes when they were not used. We required the use of distal embolic protection devices with CAS in our prior decision for the safety and protection of patients and will continue this requirement. If deployment of the distal embolic protection device is not technically possible, then the procedure should be aborted given the risks of CAS without distal embolic protection.

**● Is the evidence sufficient to conclude that PTA with carotid artery stenting improves health outcomes for patients who are at high risk for CEA surgery with asymptomatic carotid artery stenosis ≥ 80%?**

For patients who are at high risk for CEA surgery with asymptomatic carotid artery stenosis ≥ 80%, several case series or registry reports and post-approval studies have been published since our prior decision which provided restricted coverage for these patients. The basis of our restricted coverage in the prior decision was the undocumented natural history of asymptomatic stenosis on medical therapy (lack of a medical control group in past studies), the lack of long term data on CAS in these patients, and the lack of data on CAS performed outside the controlled trial setting. While the outcomes of asymptomatic carotid artery stenosis with optimal medical therapy remain unclear and unstudied, the published reports provide evidence regarding our other prior concerns. The observational studies by Halabi, Chaer, Park and Safian provided supporting evidence for CAS in patients with asymptomatic stenosis ≥ 80%. The post-approval studies, CAPTURE and CASES-PMS, provided additional evidence on 30-day outcomes and some information on 1 year outcomes. The post-approval studies also showed that CAS outcomes were similar by provider volume (experience levels) and in settings outside clinical trials. Unlike the situation with symptomatic patients, there were no trials or studies that raised concerns about the safety of CAS in asymptomatic patients with stenosis ≥ 80%.

With the published reports since our prior decision, CMS finds that the evidence is sufficient to conclude that PTA with carotid artery stenting improves health outcomes for patients who are at high risk for CEA surgery and have asymptomatic carotid artery stenosis ≥ 80%. With this, CMS proposes to remove the requirement that these procedures only be performed in a clinical trial or post approval study, based largely on the findings from CAPTURE and CASES-PMS. As with the currently covered indications, facilities performing CAS for this patient group must meet the facility requirements outlined in this NCD. As discussed above, CAS is not covered in the absence of distal embolic protection including those instances in which technical difficulties prevented deployment.

**● Is the evidence sufficient to conclude that PTA with carotid artery stenting improves health outcomes for patients who are at high risk for CEA surgery and ≥ 80 years of age?**

For patients who are ≥ 80 years of age, there is mounting evidence that the rate of death, stroke and MI after CAS is higher than for patients < 80 years. Stanziale and colleagues reported that octogenarians had a significantly higher rate of stroke, death or MI than nonoctogenarians (9.2% versus 3.4%, respectively; p=0.024). Safian and colleagues reported data that showed patients > 75 years had higher adverse outcomes than patients ≤ 75 (7.6% versus 4.8%). CAPTURE showed that patients ≥ 80 years of age had significantly higher rates of death, stroke or MI at 30 days than patients < 80 years (9.4% versus 5.3%, respectively; statistically significant, p-value <0.0001). SPACE found that patients > 75 years of age had a significantly higher rate of ipsilateral ischemic stroke and death at 30 days compared to patients ≥ 75 (11.01% versus 5.92%; exceeding the non-inferiority margin). Outcomes by age were not specifically reported by Chaer, Halabi, Mas and Park.

The consistency of these findings across the trials and studies, observed in both symptomatic and asymptomatic patients, creates concerns for the safety of older patients undergoing CAS. This is also consistent with the recognition that patients ≥ 80 years of age are at higher risk for CEA. These patients were specifically excluded from the NASCET and ACAS trials. This was also one of the high risk criteria in the SAPPHIRE trial for carotid revascularization in general. The higher incidence of adverse outcomes is particularly concerning for patients who have asymptomatic stenosis. In many of these patients, more harm than good would have come from the PTA and CAS procedure. Given the evidence, CMS proposes to continue the restriction that CAS for asymptomatic patients with stenosis ≥ 80% and who are ≥ 80 years of age be covered only in the setting of a clinical trial or post approval study for safety purposes. In addition, CMS proposes to expand this restriction to include symptomatic patients with stenosis ≥ 70% and who are ≥ 80 years of age.

**Facility Certification**
In the prior decision, CMS determined that CAS with embolic protection is reasonable and necessary only if performed in facilities and by physicians who have been determined to be competent in performing the evaluation, procedure and follow-up necessary to ensure optimal patient outcomes. Given the evidence reviewed in this reconsideration, CMS continues to believe that facility certification is necessary. Since the implementation of the prior certification process, several organizations have included the CMS facility requirements into a broader review process. In addition, the ICCS has released an evidence based guideline that discusses many of the same issues.

Facilities approved by CMS to perform CAS procedures were approved for two (2) years after attesting that they met the minimum facility standards (listed above in Section II). CMS will continue these standards. However, we did not outline in the previous NCD any details on the data analysis or the process for recertification. We have provided that information to approved facilities separately but will define the process in this decision for greater clarity.

***Data Analysis Details***
CMS places significant importance on each facility's data analysis plan. We believe that this standard is crucial to ensuring the most optimal care for Medicare beneficiaries. The type of data collected needs to be sufficient to allow facilities to draw accurate conclusions. At a minimum, we believe the data elements should answer these questions:

What is the patient's date of birth?
When was the procedure performed?
Does the patient meet high surgical risk criteria (defined below)?

- Age ≥80;
- Myocardial Infarction (MI);
- Left Ventricle Ejection Fraction (LVEF) < 30%;
- Contralateral carotid occlusion;
- New York Heart Association (NYHA) Class III or IV;
- Unstable angina: Canadian Cardiovascular Society (CCS) Class III/IV;
- Renal failure: end stage renal disease on dialysis;
- Common Carotid Artery (CCA) lesion(s) below clavicle;
- Severe pulmonary disease;
- Clinically significant cardiac disease (congestive heart failure (CHF), abnormal stress test, or need for open -heart surgery);
- Previous neck radiation;

- High cervical Internal Carotid Artery (ICA) lesion(s);
- Restenosis of prior carotid endarterectomy (CEA);
- Tracheostomy;
- Contralateral laryngeal nerve palsy.

Is the patient symptomatic (defined below)?

- Carotid Transient Ischemic Attack (TIA): distinct focal neurologic dysfunction persisting less than 24 hours;
- Non-disabling stroke: Modified Rankin Scale < 3 with symptoms for 24 hours or more;
- Transient monocular blindness: amaurosis fugax.

What was the Modified Rankin Scale score if the patient experienced a stroke?
What was the % stenosis of the stented lesion(s) by angiography?
Was embolic protection used?
Were there any complications (defined below)?

- All stroke: an ischemic neurologic deficit that persisted more than 24 hours;
- MI;
- All death.

With this NCD we are establishing that the data elements that answer these questions are necessary for standard five to be met. Most facilities will decide to collect many other data elements to answer additional questions. We encourage that.

This information needs to be collected on all patients undergoing CAS at each facility. Including only Medicare beneficiaries will significantly weaken and potentially invalidate any of the findings of the facility's data analysis.

***Facility certification and recertification***
Through this national coverage analysis, CMS has explored various options for reformulating the current facility certification and recertification plan. We are very interested in transferring this role to an outside entity, and have received a proposal from the Society for Cardiovascular Angiography and Interventions (SCAI) for assuming this responsibility. We will only transfer this role to an entity that presents a comprehensive and complete plan ready for immediate implementation. We are particularly interested in public comments regarding SCAI's proposal and the appropriateness of its use as the formal facility certification and recertification plan for CAS. The SCAI-CAP (SCAI Carotid Accreditation Program) program details are available for review. (SCAI CAROTID STENTING FACILITY ACCREDITATION PROGRAM (SCAI-CAP) [PDF, 369KB], SCAI-CAP Carotid Artery Stenting Facilities Accreditation Application and Data Forms [PDF, 95KB])

The 2005 NCD found CAS to be reasonable and necessary under certain circumstances including when performed in CMS approved facilities. Facilities are required to meet the five standards described in the Section B4 of the current NCD (20.7). We require facilities to submit verification to us that the first four standards had been met and the process they would use to meet the fifth standard—data analysis. As an alternative, facilities that were approved as trial sites for many of the ongoing clinical trials were considered to have met these standards. Until such time as we authorize another entity to certify facilities, we will continue that process.

The current NCD notified approved facilities that the certification was only valid for two (2) years. Over the last several months, we have worked with the approved facilities and various specialty societies to develop a recertification process. We have held several public meetings to assist in this process. We are formally outlining that process here.

For recertification purposes, facilities must attest to continuing to meet the original facility standards. We will require facilities to provide written documentation that the first four standards have been met. Because of the significant importance that we place on the facility's data analysis plan, we are requiring that each facility submit to us the data elements outlined above along with the Medicare identification number for Medicare beneficiaries. We will review this data to ensure that the data elements that we require are being collected and that all Medicare beneficiaries for whom we have paid claims are included in the data analysis. While not requiring patient identifiers for non-Medicare patients, we will review the data set to ensure that sufficient information has been collected on those patients as well.

To assist facilities in the recertification process, we are establishing the following process:

At 23 months after initial certification:

- Submission of a letter to CMS stating how the facility continues to meet the minimum facility standards as listed in the Medicare NCD Manual, 20.7.

At 27 months after initial certification:

- Submission of required data elements for all CAS procedures performed on patients during the previous two (2) years of certification.
- Data elements: Patients' Medicare identification number if a Medicare beneficiary;
  Patients' date of birth;
  Date of procedure;
  Does the patient meet high surgical risk criteria (defined below)?
    - Age ≥80;
    - Myocardial Infarction (MI);
    - Left Ventricle Ejection Fraction (LVEF) < 30%;
    - Contralateral carotid occlusion;
    - New York Heart Association (NYHA) Class III or IV;
    - Unstable angina: Canadian Cardiovascular Society (CCS) Class III/IV;
    - Renal failure: end stage renal disease on dialysis;
    - Common Carotid Artery (CCA) lesion(s) below clavicle;
    - Severe pulmonary disease;
    - Clinically significant cardiac disease (congestive heart failure (CHF), abnormal stress test, or need for open-heart surgery);
    - Previous neck radiation;
    - High cervical Internal Carotid Artery (ICA) lesion(s);
    - Restenosis of prior carotid endarterectomy (CEA);
    - Tracheostomy;
    - Contralateral laryngeal nerve palsy.

  Is the patient symptomatic (defined below)?

- Carotid Transient Ischemic Attack (TIA): distinct focal neurologic dysfunction persisting less than 24 hours;
- Non-disabling stroke: Modified Rankin Scale < 3 with symptoms for 24 hours or more;
- Transient monocular blindness: amaurosis fugax.

Modified Rankin Scale score if the patient experienced a stroke;
% stenosis of stented lesion(s) by angiography;
Was embolic protection used?
Were there any complications (defined below)?

- All stroke: an ischemic neurologic deficit that persisted more than 24 hours;
- MI;
- All death.

Recertification is effective for two (2) additional years during which facilities will be required to submit the data elements every April 1 and October 1.

Facilities enrolled in a CMS approved national carotid artery stenting registry will automatically meet the data collection standards required for initial and continued facility certification. Hospitals' contracts with an approved registry may include authority for the requestor to submit required data to CMS for the hospital.

The following national CAS registries are approved by CMS for data collection.

- The Society for Vascular Surgery (SVS) Vascular Registry; and
- The National Cardiovascular Data Registry – Carotid Artery Revascularization and Endarterectomy Registry (NCDR-CARE).

Additional registries may be considered for CMS approval by providing CMS with a comprehensive overview of the registry and its capabilities, and the manner in which the registry meets CMS data collection and evaluation requirements. A list of approved registries will be available on the CMS coverage website.

**CAS in Stroke Patients**
In the prior decision, CMS excluded coverage of CAS for patients with a modified Rankin score ≥ 3. This was based on the inclusion and exclusion criteria of the trials on CEA and CAS which we continue to believe is consistent with the available evidence. Carotid revascularization procedures including CEA and CAS should not be performed in patients who have had a prior disabling stroke. We are not using this scale as an outcome measure but solely as a patient selection factor.

**In the Opinion of a Surgeon**

The requestor also asked that CMS remove the language from the current NCD that requires patients eligible for CAS to be at high surgical risk in the opinion of a surgeon. We disagree. Both EVA-3S and SPACE demonstrate the risks of CAS and the benefits of CEA when preformed by well-trained, highly qualified surgeons. We believe this data clearly demonstrates the need for an expert opinion and we are thus proposing that we modify the standard to require that the patient's high risk status be determined by a surgeon credentialed to perform CEA.

In addition, CAS for patients who are not at high risk for CEA in the opinion of a surgeon credentialed to perform carotid endarterectomy remains covered only in FDA-approved Category B IDE clinical trials under 42 CFR 405.201 or under the clinical trial policy. CMS believes that the most valuable information for non-high risk patient populations will be derived from randomized clinical trials (RCTs) and prefers that trials examining these patients are RCTs. The EVA-3S and SPACE randomized trials enrolled symptomatic patients with no restriction based on risk for CEA. Since both trials failed to show non-inferiority of CAS, evidence on safety and effectiveness from randomized clinical trials is needed for patients at low surgical risk. The CREST and ACT randomized trials are ongoing and should provide additional information in the near future.

## IX. Proposed Decision

### A. Summary of Proposed Changes

The Centers for Medicare and Medicaid Services (CMS) proposes the following changes to the national coverage determination (NCD) for carotid artery stenting:

- Restrict the current coverage for patients who are at high risk for carotid endarterectomy (CEA) and have symptomatic carotid artery stenosis ≥70% to patients who are less than 80 years of age;
- Expand coverage to patients who are at high risk for CEA and have asymptomatic carotid artery stenosis ≥80% and are less than 80 years old;
- Establish that the surgeon performing the surgical consultation that determines a patient's high risk status must be properly credentialed to perform CEA as determined by the facility.

CMS proposes the following clarifications to the current NCD:

- CAS is only covered when used with an embolic protection device and is, therefore, not covered if deployment of the distal embolic protection device is not technically possible;
- The five facility certification requirements are unchanged. However, the fifth standard for facility approval is rewritten for clarity. We propose to modify the process for completing the certification and recertification process in the NCD Manual.

CMS proposes to maintain current coverage for CAS as follows:

- Patients at high risk for CEA who have symptomatic carotid artery stenosis between 50-70%;
- Patients who are ≥ 80 years of age with either symptomatic stenosis ≥70% or asymptomatic stenosis ≥ 80% in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201), the clinical trial policy (Medicare NCD Manual 310.1), or the National Coverage Determination on CAS post approval studies (Medicare NCD Manual 20.7B3);
- CAS for patients who are not at high risk for CEA in the opinion of a surgeon credentialed to perform carotid endarterectomy remains covered only in FDA-approved Category B IDE clinical trials under 42 CFR 405.201 or under the clinical trial policy.

This proposed decision only changes coverage criteria in section B4 of the Medicare NCD Manual for CAS (20.7). Coverage as determined in the other sections of 20.7 will continue without modification.

We are requesting public comments on this proposed determination pursuant to Section 731 of the Medicare Modernization Act. We are particularly interested in comments that include new evidence we have not reviewed here. After considering the public comments and any additional evidence we will make a final determination and issue a final decision memorandum.

**B. Proposed Decision**

CMS proposes to change the Medicare NCD Manual language as follows (italics indicate proposed additions/changes):

The Centers for Medicare and Medicaid Services (CMS) has determined that the evidence is adequate to conclude that carotid artery stenting (CAS) with embolic protection is reasonable and necessary for the following:

1. *Patients who are < 80 years of age, at high risk for carotid endarterectomy (CEA), and have symptomatic carotid artery stenosis ≥ 70%;*
2. *Patients who are < 80 years of age, at high risk for CEA and have asymptomatic carotid artery stenosis ≥ 80%;*
3. *Patients who are ≥ 80 years of age with either symptomatic stenosis ≥ 70% or asymptomatic stenosis ≥ 80% in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201), the clinical trial policy (Medicare NCD Manual 310.1), or the National Coverage Determination on CAS post approval studies (Medicare NCD Manual 20.7);*

4. Patients who are at high risk for CEA and have symptomatic carotid artery stenosis between 50% and 70%, in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201), as a routine cost under the clinical trials policy (Medicare NCD Manual 310.1), or in accordance with the National Coverage Determination on CAS post approval studies (Medicare NCD Manual 20.7).

*Coverage is limited to procedures performed using FDA approved carotid artery stents and embolic protection devices.*

*The use of a distal embolic protection device is required. If deployment of the distal embolic protection device is not technically possible, then the procedure should be aborted given the risks of CAS without distal embolic protection.*

Patients at high risk for CEA are defined as having significant comorbidities and/or anatomic risk factors (i.e., recurrent stenosis and/or previous radical neck dissection), and would be poor candidates for CEA in the opinion of a surgeon *credentialed to perform carotid endarterectomy*.

Significant comorbid conditions include but are not limited to:

- congestive heart failure (CHF) class III/IV;
- left ventricular ejection fraction (LVEF) < 30%;
- unstable angina;
- contralateral carotid occlusion;
- recent myocardial infarction (MI);
- previous CEA with recurrent stenosis;
- prior radiation treatment to the neck; and
- other conditions that were used to determine patients at high risk for CEA in the prior carotid artery stenting trials and studies, such as ARCHER, CABERNET, SAPPHIRE, BEACH, and MAVERIC II.

Symptoms of carotid artery stenosis include carotid transient ischemic attack (distinct focal neurological dysfunction persisting less than 24 hours), focal cerebral ischemia producing a nondisabling stroke (modified Rankin scale < 3 with symptoms for 24 hours or more), and transient monocular blindness (amaurosis fugax). Patients who have had a disabling stroke (modified Rankin scale ≥ 3) would be excluded from coverage.

The determination that a patient is at high risk for CEA and the patient's symptoms of carotid artery stenosis should be available in the patient medical records prior to performing any procedure.

The degree of carotid artery stenosis should be measured by duplex Doppler ultrasound or carotid artery angiography and recorded in the patient's medical records. If the stenosis is measured by ultrasound prior to the procedure, then the degree of stenosis must be confirmed by angiography at the start of the procedure. If the stenosis is determined to be less than 70% by angiography, then CAS should not proceed.

In addition, CMS has determined that CAS with embolic protection is reasonable and necessary only if performed in facilities that have been determined to be competent in performing the evaluation, procedure and follow-up necessary to ensure optimal patient outcomes. Standards to determine competency include specific physician training standards, facility support requirements and data collection to evaluate outcomes during a required reevaluation.

CMS has created a list of minimum standards modeled in part on professional society statements on competency. All facilities must at least meet CMS's standards in order to receive coverage for carotid artery stenting for high risk patients.

- Facilities must have necessary imaging equipment, device inventory, staffing, and infrastructure to support a dedicated carotid stent program. Specifically, high-quality X-ray imaging equipment is a critical component of any carotid interventional suite, such as high resolution digital imaging systems with the capability of subtraction, magnification, road mapping, and orthogonal angulation.
- Advanced physiologic monitoring must be available in the interventional suite. This includes real time and archived physiologic, hemodynamic, and cardiac rhythm monitoring equipment, as well as support staff who are capable of interpreting the findings and responding appropriately.
- Emergency management equipment and systems must be readily available in the interventional suite such as resuscitation equipment, a defibrillator, vasoactive and antiarrhythmic drugs, endotracheal intubation capability, and anesthesia support.
- Each institution should have a clearly delineated program for granting carotid stent privileges and for monitoring the quality of the individual interventionalists and the program as a whole. The oversight committee for this program should be empowered to identify the minimum case volume for an operator to maintain privileges, as well as the (risk-adjusted) threshold for complications that the institution will allow before suspending privileges or instituting measures for remediation. Committees are encouraged to apply published standards from national specialty societies recognized by the American Board of Medical Specialties to determine appropriate physician qualifications. Examples of standards and clinical competence guidelines include those published in the December 2004 edition of the American Journal of Neuroradiology, and those published in the August 18, 2004 Journal of the American College of Cardiology.
- To continue to receive Medicare payment for CAS under this decision, the facility or a contractor to the facility must collect data on all carotid artery stenting procedures done at that particular facility. This data must be analyzed routinely to ensure patient safety. This data must be made available to CMS upon request. The interval for data analysis will be determined by the facility but should not be less frequent than every 6 months.

Since there currently is no recognized entity that evaluates CAS facilities, CMS has established a mechanism for evaluating facilities. Facilities must provide written documentation to CMS that the facility meets one of the following:

1. The facility was an FDA approved site that enrolled patients in prior CAS IDE trials, such as SAPPHIRE, and ARCHER;
2. The facility is an FDA approved site that is participating and enrolling patients in ongoing CAS IDE trials, such as CREST;
3. The facility is an FDA approved site for one or more FDA post approval studies; or
4. The facility has provided a written affidavit to CMS attesting that the facility has met the minimum facility standards. This should be sent to:

   Director, Coverage and Analysis Group
   7500 Security Boulevard, Mailstop C1-09-06
   Baltimore, MD 21244.

The letter must include the following information:
Facility's name and complete address;
Facility's Medicare provider number;
Point-of-contact for questions with telephone number;
*Discussion of how each standard has been met by the hospital;*
Mechanism of data collection of CAS procedures; **and**
Signature of a senior facility administrative official.

A list of certified facilities will be made available and viewable at: http://www.cms.hhs.gov/MedicareApprovedFacilitie/CASF/list.asp#TopOfPage. In addition, CMS will publish a list of approved facilities in the Federal Register.

*Facilities must recertify every two (2) years in order to maintain Medicare coverage of CAS procedures. Recertification will occur when the facility documents that it continues to meet the CMS standards.*

*The process for recertification is as follows:*

*At 23 months after initial certification:*

- *Submission of a letter to CMS stating how the facility continues to meet the minimum facility standards as listed above.*

*A t 27 months after initial certification:*

- *Submission of required data elements for all CAS procedures performed on patients during the previous two (2) years of certification.*
- *Data elements: Patients' Medicare identification number if a Medicare beneficiary;*
  *Patients' date of birth;*
  *Date of procedure;*
  *Does the patient meet high surgical risk criteria (defined below)?*

- *Age ≥80;*
- *Myocardial Infarction (MI);*
- *Left Ventricle Ejection Fraction (LVEF) < 30%;*
- *Contralateral carotid occlusion;*
- *New York Heart Association (NYHA) Class III or IV;*
- *Unstable angina: Canadian Cardiovascular Society (CCS) Class III/IV;*
- *Renal failure: end stage renal disease on dialysis;*
- *Common Carotid Artery (CCA) lesion(s) below clavicle;*
- *Severe pulmonary disease;*
- *Clinically significant cardiac disease (congestive heart failure (CHF), abnormal stress test, or need for open-heart surgery);*
- *Previous neck radiation;*
- *High cervical Internal Carotid Artery (ICA) lesion(s);*
- *Restenosis of prior carotid endarterectomy (CEA);*
- *Tracheostomy;*
- *Contralateral laryngeal nerve palsy.*

*I s the patient symptomatic (defined below)?*

- *Carotid Transient Ischemic Attack (TIA): distinct focal neurologic dysfunction persisting less than 24 hours;*
- *Non-disabling stroke: Modified Rankin Scale < 3 with symptoms for 24 hours or more;*
- *Transient monocular blindness: amaurosis fugax.*

*M odified Rankin Scale score if the patient experienced a stroke;*
*% stenosis of stented lesion(s) by angiography;*
*Was embolic protection used?*
*Were there any complications (defined below)?*

- *All stroke: an ischemic neurologic deficit that persisted more than 24 hours;*
- *MI;*
- *All death.*

*Recertification is effective for two (2) additional years during which facilities will be required to submit the requested data every April 1 and October 1.*

*Facilities enrolled in a CMS approved national carotid artery stenting registry automatically meet the data collection standards required for initial and continued facility certification. Hospitals' contracts with an approved registry may include authority for the registry to submit required data to CMS for the hospital.*

*The following national CAS registries are approved by CMS for data collection.*

- *The Society for Vascular Surgery (SVS) Vascular Registry; and*
- *The National Cardiovascular Data Registry – Carotid Artery Revascularization and Endarterectomy Registry (NCDR-CARE).*

*Additional registries may be considered for CMS approval by providing CMS with a comprehensive overview of the registry and its capabilities and the manner in which the registry meets CMS data collection and evaluation requirements. A list of approved registries will be available on the CMS coverage website.*

*CAS for patients who are not at high risk for CEA in the opinion of a surgeon credentialed to perform carotid endarterectomy remains covered only in FDA-approved Category B IDE clinical trials under 42 CFR 405.201 or under the clinical trial policy.*

*CMS has determined that PTA of the carotid artery concurrent with the placement of an FDA-approved carotid stent is not reasonable and necessary for all other patients.*

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Table 1. Carotid Artery Stenting

| Author/ Year | VII. Study Design, Patient Characteristics | Demographics | Results |
|---|---|---|---|
| Chaer et al., 2006 | Observational study / Registry analysis CEA vs CAS; N=693 (545 and 148, respectively).<br>Primary outcome = death, stroke, MI within 30 days or death or ipsilateral stroke for duration of follow-up.<br>All patients were at high risk for CEA.<br>No other inclusion or exclusion criteria were specified. | Mean age = 73 yrs. | Primary outcome = 4.0% CEA; 3.4% CAS. |
| Cordis, 2006 CASES-PMS | Observational study / Registry analysis CAS; N = 1479.<br>Primary outcome = all stroke, death, MI within 30 days.<br>Symptomatic patients ≥50% stenosis by ultrasonography or angiography (n=322; 21.8%); Asymptomatic ≥80% stenosis (n=1157; 78.2%).<br>All patients were at high risk for surgery. | Mean age = 73 yrs. | Primary outcome = 4.8%.<br>Symptomatic patients = 5.9%.<br>Asymptomatic patients = 4.5%. |
| Halabi et al., 2006 | Case series CAS; N = 116.<br>Primary outcome = in-hospital death, stroke and MI.<br>All patients were at high risk for CEA.<br>Symptomatic patients ≥60% stenosis by angiography; Asymptomatic ≥70% stenosis by angiography. | Mean age = 71 yrs. | Primary outcome = 2.6% CAS. |
| Gray et al., 2006 ARCHeR | 3 case series; N =581.<br>Primary outcome = all stroke, death, MI within 30 days.<br>Symptomatic patients ≥50% stenosis by angiography (n=138; 23.8%); Asymptomatic ≥80% stenosis by angiography (n=443; 76.2%).<br>All patients were at high risk for surgery. | Mean age = 70 yrs.<br>Age≥80 =15.5%. | All stroke, death and MI = 8.3% (48/581).<br>Symptomatic patients = 13.0% (18/138).<br>Asymptomatic patients = 6.8% (30/443). |
| Gray et al., 2006 CAPTURE | Observational study / Registry analysis CAS; N = 3500.<br>Primary outcome = all stroke, death, MI within 30 days. | Mean age = 73 yrs.<br>Age≥80 =23.7%. | All stroke, death and MI = 16.9% (40/581).<br>Symptomatic patients = 13.0% (18/138). |

| Author/ Year | VII. Study Design, Patient Characteristics | Demographics | Results |
|---|---|---|---|
| | Symptomatic patients ≥50% stenosis by angiography (n=482; 13.8%); Asymptomatic ≥80% stenosis by angiography (n=3018; 86.2%).<br>All patients were at high risk for surgery. | | Asymptomatic patients = 5.4% (24/443).<br>Age≥80 = 9.4%;<br>Age<80 = 4.8%. |
| Mas et al., 2006<br>EVA-3S | Randomized noninferiority trial CEA vs CAS; N=520 (259 and 261, respectively).<br>Primary outcome = any stroke or death within 30 days.<br>All symptomatic patients with stenosis ≥60% by NASCET criteria.<br>Symptoms were hemispheric or retinal transient ischemic attack or nondisabling stroke or retinal infarct within 120 days.<br>There was no inclusion criteria based on surgical risk.<br>Patients with modified Rankin ≥3 were excluded. | Mean age = 70 yrs.<br>Age≥75 =36.3%. | Any stroke or death = 3.9% CEA; 9.6% CAS (relative risk = 2.5; 95%CI 1.2-5.1).<br>Trial was stopped early for safety and futility. |
| Park et al., 2006 | Observational study / Database analysis CEA vs CAS; N=94 (48 and 46, respectively).<br>Outcomes included death, stroke, length of stay, costs.<br>Symptomatic patients ≥50% stenosis by duplex ultrasonography; Asymptomatic ≥80% stenosis.<br>There was no inclusion criteria based on surgical risk. | Mean age = 71 yrs. | Perioperative mortality = 2% CEA; 0% CAS.<br>Stroke = 4% CEA; 2% CAS. |
| Safian et al., 2006<br>CREATE | Multicenter registry analysis CAS; N=419.<br>Primary outcome = all death, ipsilateral stroke, procedure-related contralateral stroke, MI within 30 days.<br>Symptomatic patients ≥50% stenosis by NASCET criteria (n=73; 17.4%); Asymptomatic ≥80% stenosis (n=346; 82.6%).<br>Symptoms were hemispheric TIA or stroke within 6 months.<br>All patients were at high risk for surgery. | Mean age= 74 yrs.<br>Age >75 yrs =50%. | All death, ipsilateral stroke, procedure-related contralateral stroke, MI = 6.2% (26/419).<br>Symptomatic patients MACCE = 16.4% (12/73).<br>Asymptomatic patients MACCE = 4.0% (14/346).<br>Age >75 = 7.6%;<br>Age≤75 = 4.8%. |
| SPACE Group, 2006 | Randomized noninferiority trial CEA vs CAS; N=1183 (595 and 605, respectively).<br>Primary outcome = ipsilateral ischemic stroke or death within 30 days.<br>Symptomatic patients ≥50% stenosis by NASCET criteria.<br>Symptoms were amaurosis, TIA or stroke.<br>No inclusion criteria based on surgical risk.<br>Patients with Modified Rankin > 3 were excluded. | Mean age= 68 yrs.<br>Age > 75 = 21.6%. | All ipsilateral stroke or death = 6.3% CEA vs 6.8% CAS.<br>Trial was stopped early.<br>CAS Age >75 = 11.0% (12/109);<br>CAS Age≤75 = 5.9% (29/490). |
| Stanziale et al., 2006 | Observational study / Database analysis CAS; Age ≥80 vs Age <80; N=360 (87 and 295, respectively).<br>Primary outcome = stroke, death, MI within 30 days.<br>Symptomatic patients ≥50% stenosis by NASCET criteria; Asymptomatic ≥80% stenosis. | Mean age = 69 and 83, respectively. | Primary outcome = 9.2% and 3.4%, respectively (p=0.02). |

## Appendix A: General Methodological Principles of Study Design

When making national coverage determinations, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service falling within a benefit category is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. The critical appraisal of the evidence enables us to determine whether: 1) the specific assessment questions can be answered conclusively; and 2) the intervention will improve health outcomes for patients. An improved health outcome is one of several considerations in determining whether an item or service is reasonable and necessary.

CMS normally divides the assessment of clinical evidence into three stages: 1) the quality of the individual studies; 2) the relevance of findings from individual studies to the Medicare population; and 3) overarching conclusions that can be drawn from the body of the evidence on the direction and magnitude of the intervention's risks and benefits.

The issues presented here represent a broad discussion of the issues we consider when reviewing clinical evidence. However, it should be noted that each coverage determination has unique methodological aspects.

**1. Assessing Individual Studies**

Methodologists have developed criteria to determine weaknesses and strengths of clinical research. Strength of evidence generally refers to: 1) the scientific validity underlying study findings regarding causal relationships between health care interventions and health outcomes; and 2) the reduction of bias. In general, some of the methodological attributes associated with stronger evidence include those listed below:

- Use of randomization (allocation of patients to either intervention or control group) in order to minimize bias.
- Use of contemporaneous control groups (rather than historical controls) in order to ensure comparability between the intervention and control groups.
- Prospective (rather than retrospective) studies to ensure a more thorough and systematical assessment of factors related to outcomes.
- Larger sample sizes in studies to help ensure adequate numbers of patients are enrolled to demonstrate both statistically significant as well as clinically significant outcomes that can be extrapolated to the Medicare population. Sample size should be large enough to make chance an unlikely explanation for what was found.
- Masking (blinding) to ensure patients and investigators do not know to which group patients were assigned (intervention or control). This is important especially in subjective outcomes, such as pain or quality of life, where enthusiasm and psychological factors may lead to an improved perceived outcome by either the patient or assessor.

Regardless of whether the design of a study is a randomized controlled trial, a non-randomized controlled trial, a cohort study or a case-control study, the primary criterion for methodological strength or quality is the extent to which differences between intervention and control groups can be attributed to the intervention studied. This is known as internal validity. Various types of bias can undermine internal validity. These include:

- Different characteristics between patients participating and those theoretically eligible for study but not participating (selection bias)
- Co-interventions or provision of care apart from the intervention under evaluation (confounding)
- Differential assessment of outcome (detection bias)
- Occurrence and reporting of patients who do not complete the study (attrition bias)

In principle, rankings of research design have been based on the ability of each study design category to minimize these biases. A randomized controlled trial minimizes systematic bias (in theory) by selecting a sample of participants from a particular population and allocating them randomly to the intervention and control groups. Thus, randomized controlled studies have been typically assigned the greatest strength, followed by non-randomized clinical trials and controlled observational studies. The following is a representative list of study designs (some of which have alternative names) ranked from most to least methodologically rigorous in their potential ability to minimize systematic bias:

- Randomized controlled trials
- Non-randomized controlled trials
- Prospective cohort studies
- Retrospective case control studies
- Cross-sectional studies
- Surveillance studies (e.g., using registries or surveys)
- Consecutive case series
- Single case reports

When there are merely associations but not causal relationships between a study's variables and outcomes, it is important not to draw causal inferences. Confounding refers to independent variables that systematically vary with the causal variable. This distorts measurement of the outcome of interest because its effect size is mixed with the effects of other extraneous factors. For observational, and in some cases randomized controlled trials, the method in which confounding factors are handled (either through stratification or appropriate statistical modeling) are of particular concern. For example, in order to interpret and generalize conclusions to our population of Medicare patients, it may be necessary for studies to match or stratify their intervention and control groups by patient age or co-morbidities.

Methodological strength is, therefore, a multidimensional concept that relates to the design, implementation and analysis of a clinical study. In addition, thorough documentation of the conduct of the research, particularly study's selection criteria, rate of attrition and process for data collection, is essential for CMS to adequately assess the evidence.

**2. Generalizability of Clinical Evidence to the Medicare Population**

The applicability of the results of a study to other populations, settings, treatment regimens, and outcomes assessed is known as external validity. Even well-designed and well-conducted trials may not supply the evidence needed if the results of a study are not applicable to the Medicare population. Evidence that provides accurate information about a population or setting not well represented in the Medicare program would be considered but would suffer from limited generalizability.

The extent to which the results of a trial are applicable to other circumstances is often a matter of judgment that depends on specific study characteristics, primarily the patient population studied (age, sex, severity of disease, and presence of co-morbidities) and the care setting (primary to tertiary level of care, as well as the experience and specialization of the care provider). Additional relevant variables are treatment regimens (dosage, timing, and route of administration), co-interventions or concomitant therapies, and type of outcome and length of follow -up.

The level of care and the experience of the providers in the study are other crucial elements in assessing a study's external validity. Trial participants in an academic medical center may receive more or different attention than is typically available in non-tertiary settings. For example, an investigator's lengthy and detailed explanations of the potential benefits of the intervention and/or the use of new equipment provided to the academic center by the study sponsor may raise doubts about the applicability of study findings to community practice.

Given the evidence available in the research literature, some degree of generalization about an intervention's potential benefits and harms is invariably required in making coverage decisions for the Medicare population. Conditions that assist us in making reasonable generalizations are biologic plausibility, similarities between the populations studied and Medicare patients (age, sex, ethnicity and clinical presentation), and similarities of the intervention studied to those that would be routinely available in community practice.

A study's selected outcomes are an important consideration in generalizing available clinical evidence to Medicare coverage determinations because one of the goals of our determination process is to assess health outcomes. We are interested in the results of changed patient management not just altered management. These outcomes include resultant risks and benefits such as increased or decreased morbidity and mortality. In order to make this determination, it is often necessary to evaluate whether the strength of the evidence is adequate to draw conclusions about the direction and magnitude of each individual outcome relevant to the intervention under study. In addition, it is important that an intervention's benefits are clinically significant and durable, rather than marginal or short-lived.

If key health outcomes have not been studied or the direction of clinical effect is inconclusive, we may also evaluate the strength and adequacy of indirect evidence linking intermediate or surrogate outcomes to our outcomes of interest.

**3. Assessing the Relative Magnitude of Risks and Benefits**

Generally, an intervention is not reasonable and necessary if its risks outweigh its benefits. Improved health outcomes are one of several considerations in determining whether an item or service is reasonable and necessary. For most determinations, CMS evaluates whether reported benefits translate into improved health outcomes. CMS places greater emphasis on health outcomes actually experienced by patients, such as quality of life, functional status, duration of disability, morbidity and mortality, and less emphasis on outcomes that patients do not directly experience, such as intermediate outcomes, surrogate outcomes, and laboratory or radiographic responses. The direction, magnitude, and consistency of the risks and benefits across studies are also important considerations. Based on the analysis of the strength of the evidence, CMS assesses the relative magnitude of an intervention or technology's benefits and risk of harm to Medicare beneficiaries.

**Appendix B – Public Comment References**

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[1] Evidence supporting our earlier policies is summarized in our earlier decision memoranda dated July 1, 2001, October 12, 2004, and March 17, 2005. This evidence is included in the record of our previous national coverage determinations. For the sake of brevity, we will not summarize all of the evidence supporting the policies that are being retained. Instead, we will incorporate the records of the earlier NCDs into the record of this NCD.

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